

(vi) When moved from storage and by whom and when returned to storage and by whom, including quantity amount;

(vii) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient;

(ix) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom.

(4) A current list of all individuals that have been granted access approval by the Administrator or the HHS Secretary;

(5) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and the date and time of entry;

(6) Accurate, current records created under § 121.9 or 42 CFR 73.9 (Responsible official), § 121.11 or 42 CFR 73.11 (Security), § 121.12 or 42 CFR 73.12 (Biosafety), § 121.14 or 42 CFR 73.14 (Incident response), and § 121.15 or 42 CFR 73.15 (Training); and

(7) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for 3 years and promptly produced upon request.

[70 FR 13284, Mar. 18, 2005, as amended at 77 FR 61081, Oct. 5, 2012]

§ 121.18 Inspections.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate the

premises and records to ensure compliance with this part.

§ 121.19 Notification of theft, loss, or release.

(a) An individual or entity must immediately notify APHIS or CDC upon discovery of the theft or loss of a select agent or toxin. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(ii) An estimate of the quantity stolen or lost;

(iii) An estimate of the time during which the theft or loss occurred;

(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must immediately notify APHIS or CDC upon discovery of a release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system);

(v) The location (building, room) from which the release occurred; and